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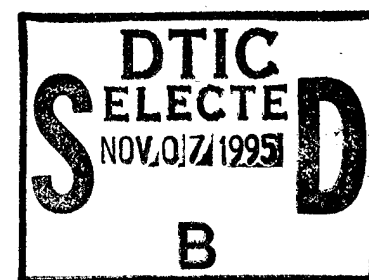
TITLE: Determinants of African American Women's Participation in Breast Cancer Prevention Research

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13. ABSTRACT (Maximum 200 words) Decisions to participate in breast cancer prevention (BCP) research and perform BCP behavior occur within the context of beliefs, perceptions, social roles and economic realities. The purpose of this research is to identify and explore factors influencing African American Women's (AAW) willingness and intention to participate in BCP research and practice BCP behavior. During the initial year of funding, eight focus groups were conducted involving a total of 45 AAW. Initial content analysis of focus group discussions revealed the following themes: 1) importance of informed consent; 2) lack of understanding regarding the placebo concept which was viewed as "unfair" treatment; 3) distrust of the research process due to feelings of being experimented on and being used as a guinea pig; 4) view of medical research as important, being a way to advance scientific knowledge if used properly; 5) view of financial compensation as a means of enabling AAW to participate in research programs, as well as demonstrating consideration for time and effort; and 6) perception that research is for people who have the disease, not for healthy people. These results suggest important direction for developing culturally relevant strategies to enhance recruitment of AAW to BCP trials.				
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Introduction: It has been widely recognized that the greatest potential for reducing breast cancer mortality may be realized through aggressive implementation of breast cancer prevention (BCP), hence, the initiation and implementation of three national breast cancer prevention clinical trials: the Women's Health Trial, NSABP Breast Cancer Prevention Trial (BCPT), and the Women's Health Initiative (1,2,3). National data indicate, however, that minority and low-income women are often underrepresented in such clinical trials (2,3). In fact, current accrual to the NSABP BCPT includes only 5% minority representation among its over 8,000 subjects (2). Unless factors influencing this limited participation can be identified and alternate strategies defined, generalizability of study results to economically disadvantaged minority women will be limited. This problem is particularly significant for African-American women given the disproportionate mortality and morbidity due to breast cancer compared to Caucasian women (4).

Decisions to participate in breast cancer prevention (BCP) research trials and perform BCP behavior occur within the context of beliefs, perceptions, social roles, economic realities and may vary within culture. Reasons for the difficult recruitment of African-American women for participation in national BCP trials has been assumed to be related to: 1) hesitancy to participate in research (ethical issues relating to efficacy, randomization, confidentiality; side effects, inconvenience and cost); 2) health professional's lack of information regarding research trials; 3) women's lack of knowledge regarding cancer prevention and opportunities for participation in research; 4) unwillingness to consider investigational trials as opportunities for participation by healthy individuals; and 5) historical barriers regarding research participation (5). There has been little verification of the impact of these assumed barriers.

Purpose: The purpose of this study is to identify and explore cognitive, social and environmental factors influencing African-American women's willingness to participate in BCP research and intention to practice BCP behavior. The objectives are to: 1) identify culturally salient beliefs and attitudes related to BCP behavior practice and research participation using a focus group technique; 2) develop a valid and reliable theoretically based instrument; and 3) identify the relative strength and interaction of factors influencing willingness to participate in BCP research and intention to practice BCP behavior via a descriptive survey.

Theoretical Framework: The theoretical basis identifying variables to be considered in this study is derived from the Health Belief Model (HBM), Theory of Reasoned Action (TRA), Social Learning Theory (SLT) and related literature organized according to the PRECEDE Health Education Planning Framework (6). These theoretical models suggest variables that have related significantly to breast cancer detection behavior in past research. Based on preliminary findings, similar factors would have applicability for explaining

willingness to participate in BCP research and perform BCP behavior (Appendix A).

Research Design and Methods: A combined qualitative and quantitative approach will be used in the research. A population of African-American women attending outpatient clinics at a large Los Angeles county hospital will be the target population for this study. Salient beliefs will be determined via 6-8 focus group sessions (N=5-10/group). An instrument will then be developed based on the major themes identified from these discussions related to consequential beliefs, social norms, and factors facilitating/inhibiting willingness to participate in BCP research and intention to practice BCP behavior. Feasibility and psychometric properties of the instrument will be determined via a pilot study (N=40) prior to the descriptive survey (N=200). Focus group data will be analyzed using manifest content analysis. Reliability and validity will be determined by the Content Validity Index, internal consistency and test-retest procedures. Descriptive survey data will be analyzed using univariate, bivariate and multivariate techniques. Findings from this study will be useful for developing culturally sensitive communication messages and intervention strategies tailored to the needs of low-income, African-American women and aimed at enhancing BCP research participation and practice.

Body: As identified in the statement of work, the task to be completed during the first year of funding related to determining the salient attitudes and beliefs of AAW concerning BCP research and practice using focus group techniques.

Eight focus groups were conducted during the initial year of funding, including one pilot focus group and seven additional focus groups involving a total of 45 AAW.

Characteristics of the participants included:

Age (Mean Years)	51.4
Range	35-91
Education (Mean Years)	12.8
Range	8-18
Marital Status	
Separated/Divorced	42.2%
Married	20.0%
Single	20.0%
Widowed	15.6%
Living Together	2.2%

Characteristics of the participants included: (con't)

Employment	
Not Employed	31.1%
Retired	22.2%
Work Part-Time	17.8%
Work Full-Time	17.8%
Disabled	4.4%
Other	6.7%
Income	
≤ \$10,000	60.5%
\$11,000 - \$20,000	25.6%
\$21,000 - \$25,000	11.6%
> \$25,000	2.3%
Health Insurance Coverage	
None	33.3%
Medicare	28.9%
Medical	20.0%
Private/HMO	17.8%

Audio tapes of the sessions were transcribed, edited and corrected. Meetings were held with research staff to review the common themes identified in the sessions for the topic areas of interest. The initial coding scheme was developed and revised and randomly selected transcripts were chosen for coding by the research team to test interrater reliability. After comparison of the coding results, the coding scheme was revised and members of the research team coded two to three focus group transcripts. Main concepts were identified to be included in the development of a survey questionnaire.

SUMMARY OF MAJOR FINDINGS

Attitudes and Beliefs about Breast Cancer and Breast Cancer Prevention: Breast Cancer prevention behavior was associated with practice of BSE, having a mammogram, and having regular breast exams. Participants identified the need for education in this area, especially among younger women. Recognition of the possibility that breast cancer might be prevented was not well understood, although a few participants did identify diet as important in possibly causing breast cancer. Knowledge of family history of breast cancer was also identified as being important.

Breast cancer was associated with death and dying, concern about body image (loss of a breast) and effect on the spouse. No really "new" insights were identified regarding African American women's beliefs and attitudes about breast cancer. The "fatalistic" attitude regarding cancer is still apparent.

Beliefs about Medical Research: Perhaps of greater interest were the attitudes and beliefs of African American women regarding medical research. Categories of responses included ethical issues in medical research, factors promoting, enabling, or inhibiting participation, avenues for communication of information about on-going research to the community, and identification of types of people who should participate in research.

In general medical research was thought to be important and effective as a mechanism for contributions to science (advance knowledge and technology, help find a cure). Humanistic beliefs were also identified: way to help others, and way to help future generations. A recurring theme identified by many of the groups was a distrust of the research process (being used as an experiment, being a guinea pig, being take advantage of, not feeling fully aware of what would be done in the research, i.e. lack of informed consent, being given a "fake" treatment (placebo), not being given effective treatment (randomization to a control group). Some of the perceived distrust of research was inseparable from the distrust of treatment received by persons who received medical care in the county system (people in the county are experimented on because it's a teaching facility, especially the older people). Participants also referred to the Tuskegee study in which African Americans were treated "unfairly", "they weren't given the treatment they needed" (a racial issue). Although research was viewed as being important, a feeling of "let someone else be first" was the common response.

When asked about concerns regarding prevention research, which would involve healthy people, responses were "it might cause disease", "people don't want to think about it unless they have the problem or are at a higher risk" (susceptibility). There was a feeling about not hurting one person, especially if they're healthy, to help another.

Research Participation: When asked who should participate in research, "people with the disease" was the most common response. Prevention research that included diet or exercise was viewed as being less threatening because of the reduced risk of having side effects. There was a lack of understanding of the concept of using a placebo in randomized clinical trials with the view that people would not be given the treatment they need. Another common view was that research should be done on animals first and then on people with the disease rather than on healthy individuals.

Factors Influencing Participation: Some of the factors identified as inhibiting participation in research included: not being aware of what is available, fear of the outcome, fear of being used as a guinea pig, time involved, cost to attend visits (transportation, lost time from work), transportation, home responsibilities such as child care, possible side effects, lack of trust in the researchers, fear of getting the disease, general attitudes of "if

it ain't broke don't fix it, in other words if there isn't a problem don't look for one". An additional theme which surfaced during transcript analysis was the patient-health care provider interaction and issues associated with receiving health care in a "county facility" (long waits, impersonal care, not enough time with the doctor) which may have a negative impact on research participation.

Factors identified as enabling or enhancing participation in research included: being able to help others; way to get close follow-up and good medical care; compensation for transportation costs, time off from work or child care; "free" health care check-ups or exams such as mammography; informed consent resulting in feeling comfortable that one knows exactly what would happen in the research; and having a doctor's recommendation to participate.

Of particular interest was the thought of compensation, not necessarily as an incentive, but as an enabling factor providing participants with funds that could be used to assist in transportation costs to attend visits, or provide care at home in their absence. Participants also mentioned that this demonstrates consideration for the individual's time and effort in participating in the program and may be a mechanism by which trust between the researcher and the participant could be enhanced. Future research examining the impact of modest reimbursement which may enhance minority participation in breast cancer clinical trials is currently being developed.

Conclusion: These preliminary focus group findings support reported literature identifying multiple factors as potentially responsible for the lack of representation of minority groups in Clinical Trials. Among AAW, knowledge of what types of research is available and the issue of compensation were considered important. These findings correspond with the recommendations resulting from the Workshop on the Recruitment and Retention of Women in Clinical Studies, i.e. increasing community awareness regarding on-going available research, making participation in clinical studies possible by using financial incentives without creating undue influence, as an appropriate recruitment tool, and conducting research to determine optimal methods and/or incentives to facilitate enrollment in clinical trials and improve compliance once enrolled (7,8).

Outcome of Research to Date: Two abstracts have been written related to findings in this research project (Appendix B). The first is entitled "Attitudes and Adherence of African American Women to Dietary Fat Intake Reduction". This was presented as a poster at the Oncology Nursing Society, 20th Annual Congress, Anaheim, California, May 1995. The second abstract is entitled "African American Perspectives about on Research Participation: Emerging Themes" submitted to the Oncology Nursing Society Annual Congress to be held in May 1996 in Philadelphia, Pennsylvania.

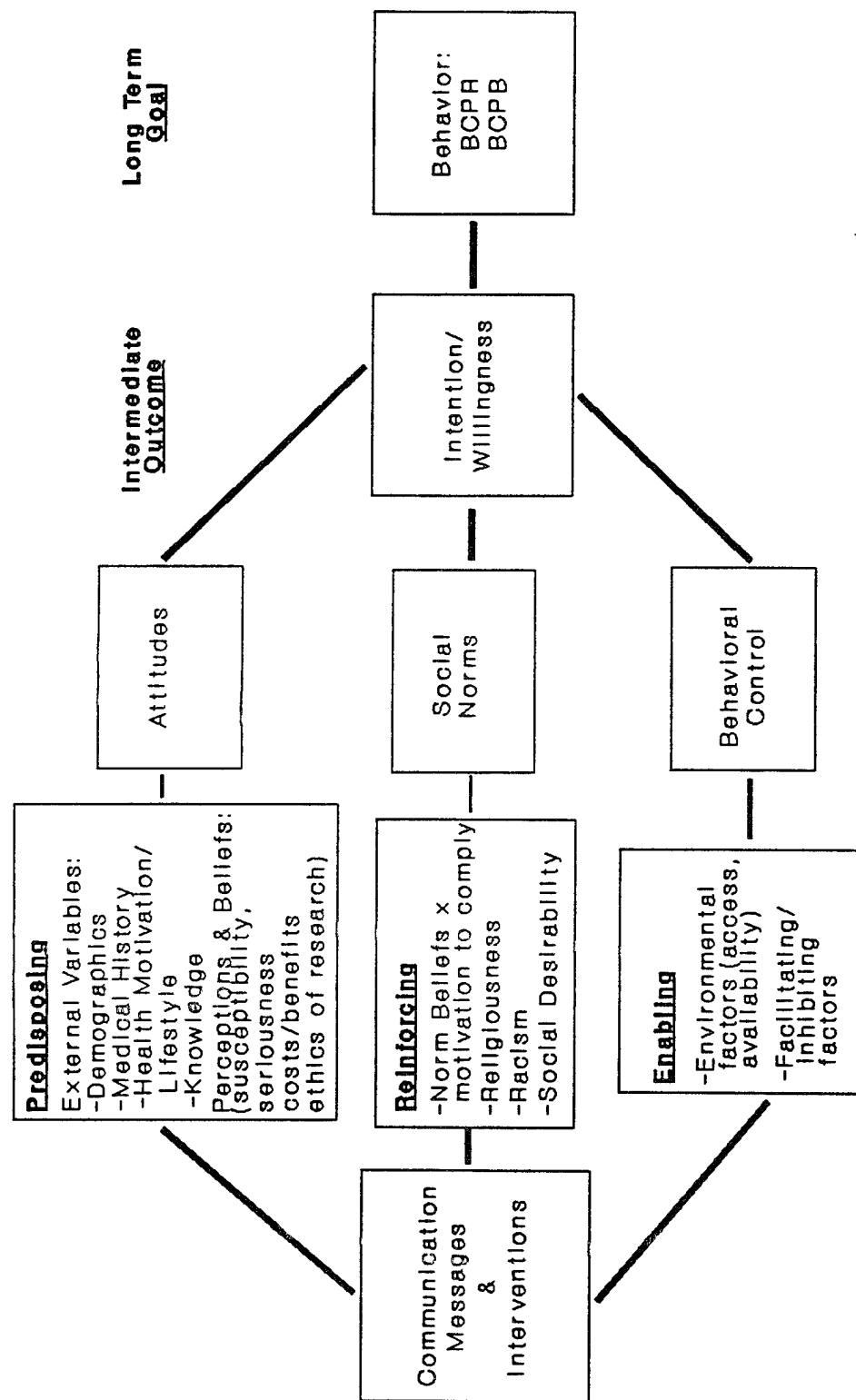
In addition, a proposal for additional funding has been submitted in response to request for applications for the National Action Plan on Breast Cancer June 14, 1995. This proposed research is based directly on findings from the focus group discussions conducted as part of this study and will evaluate the impact of a modest reimbursement/incentive as a means of enhancing recruitment of African American women in breast cancer clinical trials.

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APPENDIX A

Figure 1. Variables Potentially Impacting Breast Cancer Prevention Behavior and Research Participation



BCPR - Breast Cancer Prevention Research Participation
BCPB - Breast Cancer Prevention Behavior Practice

Table 1. Operational Definitions and Measures

<u>Variable</u>	<u>Definition</u>	<u>Measure</u>
<u>Predisposing External Variables:</u>		
Demographics	Age, education, marital status, household income, employment status, insurance status and type, and usual source of medical care.	Items to be developed.
Health Motivation/Lifestyle	Concern about general health and practice of breast cancer screening behaviors (breast self exam, physician breast exam, and mammography), smoking history and body mass index based on weight (kg)/height ($m^{1.5}$) (overweight = Body mass index $> 34Kg/M^{1.5}$).	Champion's Health Belief Model Scales, 1993 Abraham, 1983
Medical History	Current medical conditions such as diabetes, mellitus, heart disease, hypertension, other chronic conditions including other cancers and family history of breast cancer.	Items to be developed.
Knowledge	Cognitive information regarding breast cancer (risk factors, incidence) and ongoing breast cancer prevention research trials, available resources for finding out about breast cancer prevention research and awareness of breast cancer prevention behaviors.	Items to be developed.
<u>Perceptions, Beliefs and Attitudes:</u>		
Susceptibility	Perceived likelihood of contracting breast cancer.	Champion's HBM Scale, 1993
Seriousness	Perceived personal harm related to breast cancer.	Champion's HBM Scale, 1993
Costs/Benefits	Perceived advantages and disadvantages of breast cancer prevention behavior practice and research participation.	Items to be developed based on focus group findings and Champion's HBM Scale, 1993.

Ethics of Research

Beliefs about whether research is right or wrong, characteristics of individuals who participate in research, concerns about randomization, placebo controlled trials, efficacy of research, confidentiality and side effects.

Items to be developed based on focus group findings.

Attitudes

General favorable or unfavorable feeling toward BCP research and behavior mediated by specific beliefs about susceptibility, severity, benefits and costs.

Reinforcing:

Norm Beliefs x Motivation to comply

Identification of important referents and cultural norms likely to impact BCP behavior and BCP research participation, e.g. health care professionals, significant others etc.

Items to be developed based on focus group findings

Social Norms

Perceived influence of significant others and cultural norms regarding BCP behavior practice and research participation mediated by norm beliefs x motivation to comply.

Items to be developed based on focus group findings.

Religiousness

Perception of religiousness.

Religiousness Scale, Strayhorn, 1990.

Racism

Perception of racism.

Racism Perception Scale; Green, 1991.

Social Desirability

Perceived pressure to respond in a socially acceptable manner.

Social Desirability Scale, Hays, 1989.

Enabling:

Environmental factors

Availability of resources (time, cost transportation) and access to resources and referrals for participation in BCP research and practice of BCP behaviors.

Items to be developed based on focus group findings and literature.

Perceived
behavioral control

Perceived ability to perform BCP behaviors
and participate in BCP research mediated
by specific environmental facilitating
and inhibiting factors impacting BCP
research participation and BCP behavior
practice.

Items to be
developed based
on focus group
findings.

Outcome Variables:

Intention

Individual's desire and determination to
practice breast cancer prevention behavior
(diet or pill).

Items to be
developed.

Willingness

Individual's expressed interest and agreement
to participate in BCP research.

Items to be
developed.

Behavior

Preferred breast cancer prevention behavior,
diet vs pill.

Items to be
developed.

APPENDIX B

ATTITUDES AND ADHERENCE OF AFRICAN AMERICAN WOMEN TO DIETARY FAT INTAKE REDUCTION. L Lillington, M Grosvenor, I Johnson, RT Chlebowski, Harbor-UCLA Medical Center, Torrance, CA 90509

Current NCI guidelines call for reduction in dietary fat intake for the general population. In this regard, conventional dietary change programs may not be suited to the cultural needs of African American Women (AAW). To begin the process of developing appropriate intervention strategies, parallel quantitative and qualitative methods were used. First, dietary change was examined in a subset of AAW participating at Harbor-UCLA in the multi-center Women's Intervention Nutrition Study (WINS) which randomized postmenopausal patients with resected breast cancer to Dietary Control or Intervention, designed to reduce fat intake to 20% of calories using an intensive, one-on-one approach (JCO 11:2072). In addition, a series of four focus groups were conducted to identify enabling factors and barriers impacting dietary change among a convenience sample of 22 AAW without breast cancer. Dietary outcome for the WINS trial participants (N=21) indicated that a significant ($p < 0.01$) reduction in dietary fat intake was achieved in the Dietary Intervention Group in terms of: fat gram intake/day (52 ± 5 v 28 ± 4 g), % calories from fat (35 ± 2 v 20 ± 2 %), and body weight (80.8 ± 3.9 v 79.3 ± 3.2 kg) with all values, mean \pm SEM at entry v 3 mos, respectively. The magnitude of change was closely comparable to that reported for the overall 290 patient population.

Focus group discussion questions based on the Theory of Reasoned Action and Health Belief Model explored cognitive, social and environmental factors facilitating or inhibiting adoption of and adherence to dietary change behavior. AAW without breast cancer participating in the focus groups identified enabling factors for dietary change which included providing information on: "healthy" food choices and preparation (recipes), substitute seasonings to replace traditional "soul food" choices; education through community based sources (schools, churches etc.); as well as health professional recommendations. Barriers to dietary change included: a lack of focus on preventive health behavior; expectations of traditional high fat foods by family; church and social events (often serving traditional foods); and perception of increased time and cost required for a low-fat eating plan. These findings suggest that dietary change is achievable in a highly motivated population of AAW with breast cancer using an intensive dietary intervention. Extension of this success to the general population of AAW may be facilitated by attention to culturally relevant enabling factors and barriers.

AFRICAN AMERICAN PERSPECTIVES ON RESEARCH PARTICIPATION: EMERGING THEMES.
Linda Lillington, RN, DNSc, Marta Ruvalcaba, BA, Rowan T. Chlebowski, MD, PhD,
HARBOR-UCLA Medical Center, Torrance, California.

Nationally Funded Research trials aimed at breast cancer prevention in women at high risk are currently underway (Breast Cancer Prevention Trial, Women's Health Initiative). Recruitment of African American women for participation in these trials has been difficult. Without adequate representation, generalizability of findings to the African American population will be limited. Few studies have examined reasons for the lack of African American participation in clinical trials. The purpose of this study is to identify the attitudes and beliefs of African American women regarding breast cancer prevention research. The conceptual framework guiding the study is based on the Health Belief Model and Theory of Reasoned Action. Focus groups were used to explore beliefs and attitudes about breast health, breast cancer, breast cancer prevention, medical research, and ways to communicate information about research to the African American community. The groups were led by an experienced investigator using a standard focus group script. African American women without a diagnosis of breast cancer seen at the Breast Clinic of a large county hospital participated. Discussions were video and audio taped and transcribed. Eight focus groups were conducted (N = 45). Initial content analysis (Morgan 1988) of transcripts revealed emerging themes concerning participation in research: 1) importance of informed consent; 2) lack of understanding regarding the placebo concept which was viewed as "unfair" treatment; 3) distrust of the research process due to feelings of being experimented on, and being used as a guinea pig; 4) view of medical research as being important, as well as, a way to help others, to increase knowledge, and advance science if used properly; 5) view of financial compensation as important, providing funds to assist with transportation costs, and costs for child/elder care, rather than an incentive, as well as, a means of demonstrating consideration for participant's time and effort thereby promoting development of a "trusting relationship"; and 6) perception that research is for people who have the disease, not for healthy people, with participation possibly leading to development of the disease.

Although preliminary and involving a small group of respondents these results suggest important aspects of the African American view of medical research and provide direction for developing individualized and culturally relevant strategies to potentially enhance recruitment of African American women to breast cancer prevention trials. (Funded by State of California Breast Cancer Research Program).

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